DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Educational Workshops on Current Good Manufacturing Practices; Public Workshops

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshops.

SUMMARY: The Food and Drug Administration (FDA) is announcing a series of educational workshops on current good manufacturing practice (CGMP). The workshops, which will be held in collaboration with Peking University (Beijing, China) and the International Society for Pharmaceutical Engineering (ISPE), are intended to educate participants on current methods for compliance with good manufacturing practices (GMP). The workshops are being offered to help ensure effective CGMP programs and to further the common goals of FDA and providers of quality pharmaceutical products.

DATES: See table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: See table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Erik N. Henrikson, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301–827–9035, FAX: 301–827–8907, *henriksone@cder.fda.gov* or Qiang Zheng, Peking University, Beijing, China, 86–10–6275–6489, FAX: 86–10–6275–1207, *zhengqiang@pku.edu.cn.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Who Should Attend?

This announcement is directed towards professionals involved in the manufacture, control, and regulation of pharmaceutical products who will benefit from these workshops, including process/production engineers, manufacturing personnel, quality assurance/quality control and regulatory affairs professionals, consultants, regulatory investigators and CGMP compliance officials. Other entities or individuals may also be interested in attending.

B. Where and When Will These Workshops Be Held?

The location and times for the two workshops are listed in table 1 of this document.

TABLE 1.—WORKSHOP LOCATION AND SCHEDULES

Workshop Address	Dates and Local Times
Ying Jie Convention Center, Peking University, Beijing, China	December 5 through 7, 2005, from 9 a.m. to 5 p.m. each day.
Ying Jie Convention Center, Peking University, Beijing, China	April 24 through 26, 2006, from 9 a.m. to 5 p.m. each day.

C. How Can I Participate?

You can participate in person. Anyone interested in the GMP workshops can register through the contact person in the **FOR FURTHER INFORMATION CONTACT** section of this document.

D. Is There a Registration Fee for These Workshops?

Yes, a registration fee of $440 is required for this workshop. This registration fee includes workshop reference materials and meals. Government employees qualify for a discounted rate of $120.

E. How Can I Get Additional Information?

The notice of participation form, information about the workshops, and other related documents are available from the contact person in the **FOR FURTHER INFORMATION CONTACT** section of this document or from the Internet at *http://www.fda.gov/cder/meeting/CTP2005.htm.*

II. Background Information

A. Why Is FDA Cosponsoring These Workshops?

FDA is cosponsoring these 3-day workshops to provide information and training opportunities for industry as well as CGMP compliance officials.

B. What Will Be Covered?

The workshops will provide information on specific topics designed to educate and guide participants on methodologies and implementation of CGMP as applied to quality drug manufacturing. Presentations by both FDA and industry will provide a regulatory and practical perspective on the current relevant critical topics.

Dated: AUG 24 2005

August 24, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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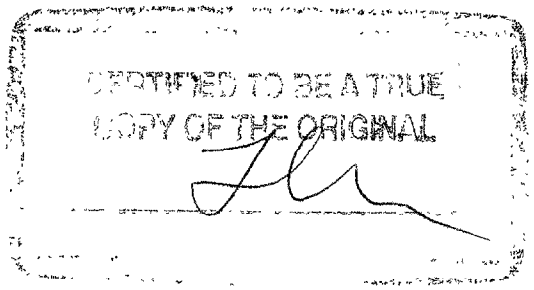

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